

## REMARKS

Any fees that may be due in connection with filing this paper or with this application during its entire pendency may be charged to Deposit Account No. 06-1050. The reference Ables *et al.* (*J. Fam. Practice*, 54:3 (2005)), accompanies this Supplemental Response.

As discussed below, Ables *et al.* was cited and discussed by Applicant in the RCE, in partial support of Applicant's arguments addressing the rejection of the pending claims on obviousness grounds. The discussion of the Ables *et al.* reference included a statement that the reference was being submitted along with the RCE. Applicant, however, inadvertently did not include the reference when filing the RCE. The instant Supplemental Response provides the Ables *et al.* reference, cited and discussed by Applicant in the RCE. Applicant notes that the RCE mailed March 12, 2007, is fully responsive to the Final Office Action mailed September 11, 2006. The instant Supplemental Response merely provides, for the Examiner's convenience, a hard copy of the Ables *et al.* reference, whose contents are discussed in the RCE.

The instant Supplemental Response also further addresses the Examiner's remarks in the Final Office Action that pertain to Applicant's duty of disclosure. In particular, the Examiner protests that, contrary to Applicant's characterizations, the previous Office Action made no comment or suggestion regarding Applicant's compliance with the duty of disclosure (*see* page 2, paragraph 2 of the Final Office Action). The same paragraph however goes on to refer to Applicant's alleged reluctance "to aid examination by pointing to any other documents of particular relevance not cited by the Examiner."

### A) The Ables *et al.* reference

In the Final Office Action, the Examiner rejected the pending claims of the instant application on obviousness grounds, over various combinations of references (*see* page 6 of the Final Office Action). In particular:

(1) Claims 1-13, 15-19, 22-26, 30, 31, 33-44 and 47-64 are rejected under 35 U.S.C. §103(a) as allegedly obvious over Leavitt *et al.* (WO 94/17405) in view of any of Johnson *et al.* (NEJM 293: 675, 1975), Meis *et al.*, (Am J Obstet Gynecol 187: S54, 2002) or Keirse (Br J Obstet Gynecol 97: 149, 1990) and further in view of Weiner *et al.* or Andersen *et al.*

(2) Claims 1-13, 15, 17-44 and 47-64 are rejected under 35 U.S.C. §103(a) as being obvious over Leavitt *et al.* in view of any of Johnson *et al.*, Meis *et al.* or Keirse, further in view of Weiner *et al.* or Andersen *et al.* and further in view of Dullien (U.S. Pat. No. 5,480,776).

(3) Claims 7, 14, 17-19 and 22-26 are rejected under 35 U.S.C. §103(a) over Leavitt *et al.* in view of any of Johnson *et al.*, Meis *et al.* or Keirse, further in view of Weiner *et al.* or Andersen *et al.* and further in view of Allen *et al.* (Exp. Biol. Med. 226: 498 (2001)) or Olsen *et al.* (Lancet 339: 1003 (1992)); and

(4) Claims 7, 14, 17-25, 30-34, 45 and 46 are rejected under 35 U.S.C. §103(a) over Leavitt *et al.* in view of any of Johnson *et al.*, Meis *et al.* or Keirse, further in view of Weiner *et al.* or Andersen *et al.*, further in view of Dullien *et al.* and further in view of Allen *et al.* (Exp. Biol. Med. 226: 498 (2001)) or Olsen *et al.* (Lancet 339: 1003 (1992)).

In the RCE, Applicant set forth the teachings of each of the cited references, then argued that none of the cited references, singly or in any combination, teaches or suggests the claimed subject matter, which is directed to combinations and methods containing components or steps, respectively, that include the particular selection of (1) a diagnostic biochemical marker for preterm delivery as the basis for identifying subjects at risk for preterm delivery; and (2) a progestational agent for delaying delivery in the subjects so identified. At page 22 of the RCE, Applicant discussed how all combinations of a diagnostic for identifying subjects at risk for preterm delivery, and a therapeutic for treating the subjects so identified, are not the same. In partial support of the argument, Applicant cited an article by Ables *et al.* (*J. Fam. Practice*, 54:3 (2005)). The article Ables *et al.* was not cited to demonstrative operativeness of the instantly claimed combinations and methods. Rather, it was cited in support of the recognition that when it comes to preterm delivery, not all diagnostic and therapeutic options are alike.

Applicant then further discussed why none of the references cited by the Examiner in the Final Office Action, singly or in any combination, teaches or suggests the selection of (1) detection of a biochemical marker for preterm delivery, such as a fetal-restricted antigen, estriol, a marker for membrane rupture, or combinations thereof, as the basis for identifying subjects at risk for preterm delivery; and (2) administration of a progestational agent as the

treatment to delay delivery in subjects so identified. Applicant concluded that the Examiner has failed to set forth a *prima facie* case of obviousness

In the RCE at page 22, Applicant stated that the Ables *et al.* reference was being submitted along with the RCE. Applicant inadvertently did not attach a copy of the reference to the RCE. Therefore, attached to the instant Supplemental Response, for the Examiner's convenience, is a copy of the Ables *et al.* reference.

**B) Applicant's Duty of Disclosure**

In a previous Office Action, mailed February 13, 2006, the Examiner alleged that the Information Disclosure Statement filed October 5, 2004, in connection with the above-captioned application contained irrelevant documents that made it impossible to identify patents and publications of particular relevance. In response, Applicant protested the implication that there was any violation of Applicant's duty of disclosure under Rule 37 CFR §1.56. In the Final Office Action, the Examiner denied that the previous Office Action contained any comment or suggestion that pertained to Applicant's duty of disclosure. The Examiner however referred to Applicant's response as allegedly indicating an unwillingness on Applicant's part to assist the Examiner by pointing to documents of relevance.

As noted by the undersigned in the RCE responsive to the Final Office Action, the Examiner appears to be implying that, by allegedly refusing to "aid" the Examiner by pointing to documents of "particular relevance," a duty has been violated by Applicant in connection with the prosecution of this application. As also noted in the RCE, Applicant and the undersigned vigorously oppose such an implication.

Applicant and the undersigned take their duty of candor very seriously and in no way have attempted to bury or otherwise hide material information from the Office, nor have they been uncooperative with the Patent Office in violation of **any** duty. In the instant application, Applicant has submitted, in Information Disclosure Statements and on Forms PTO-1449, information that may be material to the patentability of the instant claims. The term "information" as used in 37 CFR §1.56, includes *any* information that is "material to patentability." In addition to prior art such as patents and publications, "information" under 37 CFR §1.56 includes, for example, information on possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another and inventorship conflicts. See, *e.g.*, MPEP § 2001.04:

**“Materiality is not limited to prior art but embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent.”** *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234, 66 USPQ2d 1481, 1486 (Fed. Cir. 2003) (emphasis in original and emphasis added).

The undersigned has systematic procedures in place to ensure that all information that may be material to patentability, on any basis, is provided to the Office. Such information includes art cited in the specification, which is incorporated by reference into the specification and hence is relevant as being part of the specification. Other information includes references cited in related U.S. and foreign applications. Also cited are related and/or co-pending applications and issued patents of the Applicant, and/or those that are assigned to the Assignee of the instant application. Applicant notes that there is a large family of related and/or co-pending applications/patents, and a large body of literature that is related to subject matter of the instant application. The application is directed to the selection of a diagnostic for preterm delivery that identifies subjects for administration of a progestational agent. Related information includes, for example, applications/patents and references directed to the detection of biochemical markers of preterm delivery, such as fetal fibronectin and estriol, and those directed to the administration of progestational agents and/or tocolytic agents. The undersigned, on behalf of the Applicant, has taken care to ensure, to the best of the undersigned's and Applicant's knowledge and ability, that all such information has to been provided to the Examiner, pursuant to the requirements of the duty of disclosure under 37 CFR §1.56.

By following a systematic process of assessment and review as discussed above, Applicant and the undersigned have diligently endeavored to comply with the requirements of the duty of disclosure. It is not incumbent upon Applicant to “aid examination” beyond satisfying the duty of disclosure as set forth in 37 CFR §1.56. It is Applicant's belief that all pending claims are allowable. In fact, as noted previously by Applicant, according to MPEP Section 2001.04, patent applicants are advised to “submit information **for consideration by the Office in applications rather than making and relying on their own determinations of materiality.**” (emphasis added) Therefore, it is contrary to the policies and rules set forth by the Patent Office to invite Applicant to “aid in examination” of their application by assessing materiality.

Moreover, it respectfully is submitted that neither Applicant, nor the undersigned, can predict what the *Patent Office*, or a trier of fact in a later litigation, will deem material to patentability. Such a determination is a legal conclusion, to be made by the Office. To require Applicant to do so not only is contrary to the rules, but it puts Applicant in an untenable position. As is apparent, if Applicant is required to point to references of "particular relevance," the choices necessarily would imply that references not "picked" by Applicant are those that Applicant believes would not be considered as material to patentability. As the Courts consistently have held, any information withheld by Applicant as not particularly relevant, if subsequently found by a Court to constitute information that a reasonable Examiner in fact would consider important (*i.e.*, material), can be grounds for inequitable conduct. As recently as last month, the Court of Appeals of the Federal Circuit held that when Applicant did not disclose information regarding tests that were conducted on compounds of the class being claimed in the application, the actions constituted inequitable conduct even though Applicant believed the information to not be of particular relevance because the tests were conducted under conditions that were different from those described in the application (*Cargill v. Canbra Foods*, Case No. 2006-1265, -1302, Fed. Cir. February 14, 2007). The Court held that Applicant's beliefs regarding materiality were not relevant, nor was it relevant that the claims may have been patentable regardless of the information. Rather, the standard was whether a reasonable *Examiner* would consider the information to be important in a determination of patentability. Applicant therefore respectfully submits that the Examiner's expectation that Applicant and/or the undersigned must assist in a determination of what the Patent Office will deem material, is inapt and in fact interferes with Applicant's ability to satisfy the duty of disclosure and not be subject to liability.

Furthermore, as noted in the RCE, Office rules and procedures require that the Examiner *not* comment upon duty of disclosure issues. See, *e.g.*, MPEP 2010. It therefore is respectfully submitted that the comments made in the previous Office Action dated February 13, 2006, and in the Final Office Action, are inappropriate and should be withdrawn. Applicant respectfully requests that in the next Action, the Office affirmatively withdraw the statement regarding Applicant's alleged unwillingness or indifference when it comes to assisting in citation of the most pertinent art.

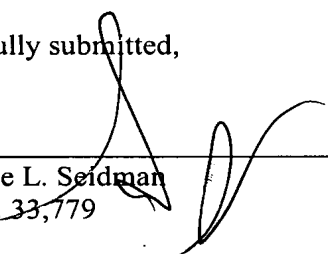
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Applicant : Hickok *et al.*  
Serial No. : 10/774,144  
Filed : February 6, 2004  
Supplemental Response

Attorney's Docket No.: 17101-025001 / 826

In view of the above remarks and the amendments and remarks of record,  
reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,



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